

MAINE COMPANY SUCCESSFULLY TRANSITIONS TO ISO 9001:2015 AND ESTABLISHES CGMP FOR NEW PRODUCT LINE

ABOUT CASCO BAY MOLDING. Founded in 2000, Casco Bay Molding is an ISO Certified product development and manufacturing company specializing in technically challenging, high volume injection-molded thermoplastic and liquid silicone rubber parts, short run - prototype silicone parts, and over-molding silicone onto plastic & metal. They currently employ 25 people at their Sanford, ME facility.

THE CHALLENGE. Casco Bay Molding recognizes the importance of a formal quality management system. They have been registered to the ISO 9001 standard since the early 2000s. Senior management wanted to maintain their ISO 9001 status yet lacked the internal expertise to transition to the new 2015 version. They reached out to Maine MEP, part of the MEP National Network™, for assistance. In addition to ISO 9001, CBM needed assistance in upgrading a product line that had received FDA clearance and required compliance with cGMP and ISO 13485.

MEP CENTER'S ROLE. Maine MEP worked closely with key employees for ISO 9001 clause interpretation, and internal auditor training to prepare for compliance with the ISO 9001:2015 version of the standard. With a new product line requiring compliance with cGMP/ISO 13485, Maine MEP trained and assisted with documentation and process updates.

To partially offset implementation cost, CBM leveraged Make It In America grant funds in the fall of 2016. The quality management system was updated to include those procedures and processes that are required by ISO 13485 and other regulatory agencies.

Early in 2018 CBM reached out to York County Community College for ISO 9001 training assistance. Maine MEP was selected as the training resource to help CBM learn about the changes to ISO 9001:2015. Six internal auditors were taught the changes to the standard and also assisted in the updating of the existing ISO 9001 quality management system documentation. In May 2018 CBM passed their ISO 9001:2015 transition audit which is important to the company's marketing efforts in attracting new customers.

RESULTS



Achieved ISO 9001:2015 Transition Certification



Established ISO 13485/FDA cGMP Quality System for Medical Device Production



Increased Sales by **\$163,000**



Retained Sales by **\$15,000**



Invested **\$76,000** in necessary investments and avoided \$12,000 in unnecessary investments

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MAINEMEP 

"Since 2001 Casco Bay Molding has worked with Maine MEP to develop and evolve our ISO Quality system. Starting with ISO 9001, through medical device FDA Clearance and on to ISO 13485 Maine MEP has been a valuable partner in our growth from 3 people to 25 people, including our joint venture tool and mold shop.

Over the years, Maine MEP has greatly assisted Casco Bay Molding via identification of grant opportunities including:

- MTI Grants
- Efficiency Maine machine purchase matching grant
- Make it in America grant
- Maine Quality Centers (YCCC) employee training grant
- NETAAC

Employee training is critical to our ability to develop and manufacture silicone and thermoplastic products for our domestic and international customer base. We are grateful to have Maine MEP as part of our team. "

-Andrew Powell, President